

# EXHIBIT N

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In Re:

Bair Hugger Forced Air Warming  
Products Liability Litigation

This Document Relates To:

All Actions

MDL No.

15-2666 (JNE/FLM)

VIDEOTAPED DEPOSITION

OF

CHRISTOPHER NACHTSHEIM

Minneapolis, Minnesota

Tuesday, November 29, 2016

Reported by:

Amy L. Larson, RPR

Job No. 113495

NACHTSHEIM  
 APPEARANCES:  
 ON BEHALF OF 3M:  
 CHRISTIN GARCIA, ESQUIRE  
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 2200 Wells Fargo Center  
 90 South Seventh Street  
 Minneapolis, MN 55402

DEBORAH LEWIS, ESQUIRE  
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FOR THE PLAINTIFF:

MICHAEL SACCHET, ESQUIRE  
 CIRESI CONLIN  
 225 South Sixth Street  
 Minneapolis, MN 55402

ALSO PRESENT: Kraig Hildahl, Videographer

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1 NACHTSHEIM  
2 THE VIDEOTAPED DEPOSITION OF CHRISTOPHER  
3 NACHTSHEIM, taken on this 29th day of November,  
4 2016, at the Law Offices of Faegre Baker  
5 Daniels, LLP, 2200 Wells Fargo Center, 90 South  
6 Seventh Street, Minneapolis, Minnesota, commencing  
7 at approximately 9:11 a.m.  
8

## P R O C E E D I N G S

10  
11 THE VIDEOGRAPHER: This is the  
12 Start of tape labeled number 1 of the  
13 videotaped deposition of Christopher  
14 Nachtsheim in the matter of In Re: Bair  
15 Hugger Forced Air Warming Products Liability  
16 Litigation in the U.S. District Court for the  
17 District of Minnesota, Case Number 15-2666  
18 (JNE/FLM).

19 This deposition is being held at the  
20 Faegre Baker law firm in Minneapolis,  
21 Minnesota, on November 29th, 2016. We are  
22 going on the record at 9:11 a.m. My name is  
23 Kraig Hildahl, I'm the legal video specialist  
24 from TSG Reporting. The court reporter is  
25 Amy Larson also in association with

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1 NACHTSHEIM  
2 TSG Reporting.  
3 Will counsel please introduce  
4 themselves for the record.  
5 MS. GARCIA: Christin Garcia,  
6 counsel for defendants 3M and Arizant.  
7 MS. LEWIS: Deborah Lewis also  
8 counsel for defendants 3M and Arizant.  
9 MR. SACCHET: Michael Sacchet for  
10 plaintiffs.  
11 THE VIDEOGRAPHER: Will the court  
12 reporter please swear in the witness and then  
13 we can proceed.  
14  
15 CHRISTOPHER NACHTSHEIM,  
16 a witness in the above-entitled action,  
17 after having been first duly sworn, was  
18 deposed and says as follows:  
19

## E X A M I N A T I O N

20  
21 BY MS. GARCIA:  
22 Q. Hello, Professor Nachtsheim.  
23 A. Hello.  
24 Q. Thank you for coming here today. Could you  
25 start by, for the record, just providing your

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1 NACHTSHEIM  
2 full name and spell your last name and let us  
3 know your address.  
4 A. Christopher John Nachtsheim. And it's N as  
5 in north, A-C-H-T, S as in Sam, H-E-I-M.  
6 Address is 1789 Summit Avenue, St. Paul,  
7 Minnesota 55105.  
8 Q. Thank you. Have you ever been deposed  
9 before?  
10 A. Yes.  
11 Q. Okay. The one rule of deposition I just want  
12 to reinforce today is if you have any  
13 difficulty understanding -- well, if you  
14 don't understand my question, if you would  
15 like me to clarify something, will you please  
16 let me know that?  
17 A. Uh-huh. Yes.  
18 Q. Yes?  
19 A. Yes.  
20 Q. There's rule number 2.  
21 A. That's rule number 2, I knew that.  
22 Q. You will need to say things out loud so that  
23 we can get an accurate transcription of the  
24 record in writing where your head movements  
25 can't be taken down, and then we will try not

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1 NACHTSHEIM  
 2 object to the form of the question.  
 3 THE WITNESS: I -- I read this --  
 4 MR. SACCHET: I can walk through  
 5 it slower.  
 6 THE WITNESS: Well, I read this to  
 7 say that in March 2009 there was a change to  
 8 the combination of the two drugs you've  
 9 pronounced, and I don't believe there were  
 10 any changes until the end of the study.  
 11 MR. SACCHET: Okay.  
 12 BY MR. SACCHET:  
 13 Q. So -- so we're clear, there was a period in  
 14 which Gentamycin was applied to some  
 15 forced-air warming patients, and then the  
 16 antibiotic changed to a combination of  
 17 Gentamycin and Teicoplanin that applied to  
 18 some forced-air warming patients and all of  
 19 the conductive fabric warming patients,  
 20 correct?  
 21 A. Correct.  
 22 Q. Assuming the change in antibiotic did not  
 23 affect infection rates between warming  
 24 devices, would you still consider the  
 25 antibiotic a confounding variable?

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1 NACHTSHEIM  
 2 MS. GARCIA: Object to the form of  
 3 the question.  
 4 THE WITNESS: I'm going to assume  
 5 that it has -- the change had no effect?  
 6 BY MR. SACCHET:  
 7 Q. Yeah, assume that the antibiotic had no  
 8 effect on the infection rate. Would it still  
 9 be a confounding variable?  
 10 MS. GARCIA: Object to the form of  
 11 the question.  
 12 THE WITNESS: I don't think it  
 13 would be -- I don't think it would be  
 14 considered a confounding variable. I'm  
 15 trying to think of how else it might have an  
 16 impact, if it's not having an effect. I  
 17 guess it -- no, I don't think it would be,  
 18 yeah.  
 19 BY MR. SACCHET:  
 20 Q. One way that we could control for the -- let  
 21 me strike that.  
 22 In order to determine whether the  
 23 antibiotic had an effect on infection rates,  
 24 we could control for the warming device --  
 25 A. Yes.

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1 NACHTSHEIM  
 2 Q. -- and evaluate whether infection rates  
 3 between the changed antibiotic stayed the  
 4 same or went up or down --  
 5 A. Correct.  
 6 Q. -- with that control device, correct?  
 7 A. (Nods head.)  
 8 MS. GARCIA: I'm going to object  
 9 to the form of the question.  
 10 BY MR. SACCHET:  
 11 Q. Did you understand it?  
 12 A. Yes.  
 13 Q. If infection rates between the two groups  
 14 were similar, that would tend to show that  
 15 the antibiotic was not a confounding factor?  
 16 A. Correct.  
 17 MS. GARCIA: Object to the form of  
 18 the question.  
 19 BY MR. SACCHET:  
 20 Q. Assume that Mr. Albrecht, who you previously  
 21 mentioned was an expert in statistics and you  
 22 had full confidence in his ability to analyze  
 23 data presented in this article, informed you  
 24 that he found a 2.8 percent infection rate in  
 25 those who received Gentamycin, a single drug,

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1 NACHTSHEIM  
 2 but 3.1 percent of patients who received the  
 3 combination of antibiotics, but also  
 4 forced-air warming patients, with a nearly  
 5 identical infection rate, would you determine  
 6 that the antibiotic was a confounding factor?  
 7 MS. GARCIA: Object to the form of  
 8 the question.  
 9 THE WITNESS: That would be strong  
 10 evidence that it was not a confounding  
 11 factor.  
 12 MR. SACCHET: Let's mark this.  
 13 (Whereupon, Exhibit 27 was  
 14 marked for identification.)  
 15 BY MR. SACCHET:  
 16 Q. So just to be clear, if we look at this table  
 17 that's presented here, we can see in the  
 18 first line it presents antibiotic protocol 1  
 19 versus 2 for FAW, does it not?  
 20 A. It does.  
 21 Q. Assume that protocol 1 is the singular  
 22 antibiotic, i.e. Gentamycin, and that  
 23 protocol 2 is the combination of Gentamycin  
 24 and Teicoplanin.  
 25 A. Uh-huh. Yes.

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Q. In this particular analysis, forced-air warming is held constant, correct?

A. Correct.

Q. And for forced air, protocol 1, the percent of patients developing infection was 2.8?

A. Correct.

Q. And for forced air, protocol 2, involving patients who received both Gentamycin and Teicoplanin, the infection rate was 3.1, correct?

A. Correct.

Q. And the p-value was 0.839, correct?

A. That's what's reported here.

Q. That's what's reported here. We could conclude, based on this data set of these numbers, that when the patient-warming device is held constant, that the change in antibiotic had no effect on infection rates, correct?

MS. GARCIA: Object to the form of the question.

THE WITNESS: Assuming there's sufficient power in those sample sizes, although they look fairly large to me, yes.

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BY MR. SACCHET:

Q. The patient population for forced-air protocol 1 was 389 patients, correct?

A. Correct.

Q. And the patient population for those receiving the combination was 678, correct?

A. Correct.

Q. Those are fairly large patient populations, correct?

A. Correct.

MS. GARCIA: Object to the form of the question.

BY MR. SACCHET:

Q. Another way to determine whether the antibiotic was a confounding variable would be to control the antibiotic, but evaluate different infection rates between different forced-air -- or different warming devices, correct?

A. Yes.

MS. GARCIA: Object to the form of that question also.

BY MR. SACCHET:

Q. And if the infection rates were still higher

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among those who received forced-air warming compared to those who received conductive fabric warming, that would tend to show the antibiotic did not substantially affect infection rates, correct?

A. Correct.

MS. GARCIA: Object to the form of the question.

BY MR. SACCHET:

Q. And if that's true, the change in antibiotic would also not be a confounding factor, correct?

A. Correct.

MS. GARCIA: Object to the form of the question.

BY MR. SACCHET:

Q. If I could --

MR. SACCHET: Could I ask your basis for the objection?

MS. GARCIA: I'm sorry?

MR. SACCHET: Could I ask your basis for the objection on form?

MS. GARCIA: Yes. You keep using the word, "determine," and you keep using the

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word, "show," and you keep using the word, "establish," and I'm objecting to the form of the question based on those terms.

MR. SACCHET: That's not going to pass muster in the court.

BY MR. SACCHET:

Q. As to the hypothetical I just presented, if you could turn your attention to the second line of the table.

MS. GARCIA: I'm sorry, to just be complete with my form objection, it's also an incomplete hypothetical.

MR. SACCHET: Fair enough.

BY MR. SACCHET:

Q. Antibiotic protocol 2 involved a combination have Gentamycin and Teicoplanin, correct?

MS. GARCIA: Object to

foundation --

BY MR. SACCHET:

Q. -- for the sake of --

A. Yes.

MS. GARCIA: Excuse me. Object to foundation for that.

BY MR. SACCHET:

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Q. And the data here shows that 3.1 percent of patients who received forced-air warming in the combination antibiotic developed joint infections, correct?

A. Correct.

Q. Whereas, .9 percent of patients who received conductive fabric warming and the combination of antibiotics developed joint infections, correct?

A. Correct.

Q. By holding the antibiotic constant and discontinuing the use of forced-air warming, that resulted in a 71 percent decrease in joint infections, did it not?

MS. GARCIA: Object to the form of the question.

THE WITNESS: Yes, it did.

BY MR. SACCHET:

Q. That essentially matches the 73 percent decrease in infections that was noted in the McGovern article itself, does it not?

A. Correct.

MS. GARCIA: Object to the form of the question.

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BY MR. SACCHET:

Q. And based on the p-value of .0008, which is far less than .05, you would determine that difference to be statistically significant, would you not?

A. I would.

Q. So whether we control for the device or control for the antibiotic, based on this data set in Exhibit 27, would you determine that the antibiotic was not a confounding factor?

MS. GARCIA: Object to the form of the question, it's a lack of foundation, it's an incomplete hypothetical.

THE WITNESS: This data certainly supports that hypothesis.

BY MR. SACCHET:

Q. And if it were not a confounding factor, would there be any reason to deselect patients from the population of 1,437 accounted for in the McGovern study in order to exclude those who received a single antibiotic?

A. No.

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MS. GARCIA: Object to the form of the question.

BY MR. SACCHET:

Q. And if we were to do that and reduce the population, let's say, from the 1,473, or 37, I've forgotten which number it is, down to a number of let's say 500 patients, there could be concern about the powering of that population?

A. There could. There could be.

Q. Another confounding factor that was discussed this afternoon was a change in the thromboprophylaxis protocol, correct?

A. Yes. Can -- can you just remind me where that --

Q. Yeah, if we could turn to page 1540.

A. (Complies.)

Q. If you look at the bottom of the first full paragraph in the left-hand column, it states the thromboprophylaxis regimen from July 2008 to the end of July 2009 was Tinzaparin.

A. Uh-huh.

Q. Then it says from August 2009 to February

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2010, Rivaroxaban, which I'll represent is otherwise known as Xarelto, was provided from day one, but in February 2010 to the end of this study, patients were reverted to Tinzaparin, correct?

A. Yes.

Q. Assuming the change in the prophylaxis did not affect infection rates during the time of this study, i.e., Exhibit 4, would you still consider it a confounding variable?

A. No.

MS. GARCIA: Object to the form of the question.

(Whereupon, Exhibit 28 was marked for identification.)

MS. GARCIA: What number are we on?

MR. SACCHET: Twenty-eight, I believe.

THE COURT REPORTER: Correct.

MS. GARCIA: Thank you.

BY MR. SACCHET:

Q. Have you seen this document before, Professor?



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p-value was a statistically significant value, correct?

A. Yes, correct.

Q. So there were fewer wound complications as a result of the use of a low weight molecular heparin --

A. Correct.

Q. -- compared to Rivaroxaban, correct?

A. Yeah, correct.

MS. GARCIA: Object to the form of the question.

BY MR. SACCHET:

Q. However, the study notes that rates for RTT, which we established to be a return to theater for --

A. Uh-huh.

Q. -- infections, were not significantly different; do you see that?

A. Correct. Yes, I do.

Q. Assuming the truth -- well, let me back up.

Would you also agree that the McGovern study, Exhibit --

MS. GARCIA: Four.

BY MR. SACCHET:

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Q. -- 4, evaluated joint infections?

A. Yes.

Q. It did not evaluate wound complications, did it?

A. Correct, it did not.

Q. Assuming the truth of this study, would you ultimately agree that the change in protocol from Tinzaparin, which is an LMWH, to Xarelto, otherwise known as Rivaroxaban, and then back to Tinzaparin, did not significantly affect the infection rate?

MS. GARCIA: Object to the form of the question, to lack of foundation, and it's an incomplete hypothetical.

THE WITNESS: Assuming the study was carefully done and generalizable, yes.

BY MR. SACCHET:

Q. And assuming the study was well done and generalizable, would you agree that the change in thromboprophylaxis noted in the McGovern study, Exhibit 4, did not confound the infection rates?

MS. GARCIA: Object to the form of the question.

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THE WITNESS: Assuming -- yes.

BY MR. SACCHET:

Q. And would you also conclude that, assuming the truth of this study, it would be improper to deselect all of the patients who received Xarelto, otherwise known as Rivaroxaban, from the patient population if the thromboprophylaxis was not a confounding variable?

MS. GARCIA: Object to the form of the question.

THE WITNESS: It doesn't seem justified in -- on the basis of these results.

BY MR. SACCHET:

Q. And, in fact, when the coauthors of the McGovern study were in the process of publication, are you aware that at numerous times they sought to collect additional data in support of the study?

A. I was not aware of that. I knew that -- I knew that they sought to run this study out in time.

Q. Are you aware that when Mr. Albrecht and

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Dr. Reed collected additional data that went beyond January 2011 in the conductive fabric warming population, that the data still showed a significant decrease in infections when conductive fabric warming was used?

A. I'm aware of that.

Q. Assuming that --

MS. GARCIA: Can we take a break shortly?

MR. SACCHET: Yeah, give me two minutes.

BY MR. SACCHET:

Q. Assuming that neither the antibiotic nor the thromboprophylaxis protocol required control because they were not confounding factors as we discussed, you would be confident in the results of the observational study presented in the McGovern data?

MS. GARCIA: Object to the form of the question.

THE WITNESS: I'm confident that those weren't confounding factors, that those studies are well done. It doesn't rule out the potential for other confounding factors.